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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,281	10/13/2000	Hyun Kim	GI 5387	9127

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EXAMINER
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WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/687,281

Applicant(s)

KIM ET AL.

Examiner

Jon P Weber, Ph.D.

Art Unit

1651

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

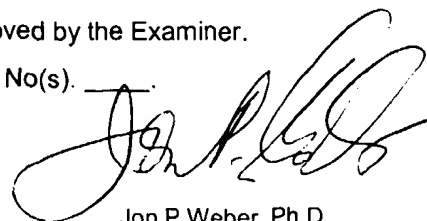
Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-7 and 11.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_



Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit: 1651

***Amendment After Final not Entered***

The amendment filed 20 October 2003 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: The proposed amendment raises new issues that would require further consideration and/or search.

The new language is broader than the old language. This is not simply a case of semantics. The old language required that the composition itself is injectable since this was an actual attribute of the composition. The instant language allows for the attribute to be intended and does not require that the composition be in injectable form. This is clearly broader.

***Claim Rejections - 35 USC § 103***

It is argued that evidence has not been provided to substantiate the disagreement with the Kim Declaration. It is insisted that examiner provide evidence or an affidavit. Statements alleged to require substantiation are: 1) Liquids do not have porosity, solids do. 2) Thick paste is injectable given 1) a larger needle, and 2) a means to force the paste through the needle. The latter is readily accomplished by using a device like a caulking gun. 3) The solvents used in Valenti et al. are alleged to be toxic and/or not pharmaceutically acceptable.

The request for an affidavit will not be acquiesced. Minimal evidence that should be known even to ordinary persons is discussed below as well as evidence from readily available information on the Internet.

The first allegation is so well known that non-technical persons are familiar with the concept. Liquids fill the pores of solids. Bubbles of gases can create temporary and moving voids

in the liquid. In a liquid that is sufficiently liquid to inject, bubbles should pass through. However, it is not generally known that bubbles correspond to porosity because they are unstable as to number, location and size.

The second allegation is known to anyone who has ever done home repairs. Caulks are often very viscous materials and yet are injectable. The fact that one might need to make an incision into a patient is of no matter to the claims at hand. The size of the needle has never been indicated. Needles can vary greatly in diameter. Even fairly viscous material can be passed through small needles under the right conditions. Persons of ordinary skill in the art can adjust such matters as needed.

The third allegation is contrary to the state of the art. In Valenti et al., the most common solvent used in the examples was DMSO. This solvent is well known to be injectable when it is of pharmaceutical grade (see [www.dmsso.org](http://www.dmsso.org) for examples). Of course, the grade of DMSO commonly available to consumers through the Internet is not advised for injection. However, medical practitioners will have access to pharmaceutical grade. DMSO is advised to be quite safe and non-toxic, contrary to the argument in the response.

Applicant's arguments filed 20 October 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103 is adhered to for the reasons of record and the additional reasons above.

### ***Propriety of Final Rejection***

It has been argued that examiner introduced new arguments that applicant should have been given a chance to respond and that finality was therefore improper.

The response fails to point out which arguments are new and not merely made in rebuttal to the previous response. The only new arguments presented are addressing the Declaration of Kim. It is proper and necessary to address the issues raised by a Declaration. This does not mean that the Office action cannot be made final.